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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,020	01/16/2004	Charles J. Davidson	S63.2N-12024-US05	5771

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EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,020	DAVIDSON ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9-12 and 22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9-12 and 22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The Preliminary Amendment filed April 3, 2006 has been entered. Claims 1, 10, 12 and 22 have been amended. New claims 23-28 have been added.

Priority

The claims receive priority benefit of parent application 09/669,060 filed September 22, 2000. The claims do not receive priority benefit of provisional application 60/155,611 filed September 23, 1999 because they are not fully supported by the provisional application. The effective filing date of the claims is September 22, 2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 9-11,22,23,24,26,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (USPN 6,048,361 as cited in applicant's IDS) in view of Jang et al (USPN 5,749,848 as cited in applicant's IDS).

Von Oepen discloses a stent delivery system for use in a body lumen with all the elements of claim 1, but is silent to an ultrasound transducer being disposed near the catheter body distal end. See Figure 3 for catheter (30) comprising a catheter body

having a distal end, proximal end, a longitudinal axis and a lumen, an expansion device (balloon) disposed near the catheter body distal end, and a stent (20) disposed over the expansion device. See Figure 2 and column 2, lines 66-67 for the stent (20) having a wall comprising struts and connectors forming multiple passageways (21) and further comprising a side hole (22) that is adapted to provide access to a side branch. Jang et al. teaches a stent delivery system, which includes an ultrasound transducer (75) disposed inside an expansion device (as required by claim 3) in order to determine exactly where the diseased segment of the blood vessel begins and ends and to image the stent for correct positioning and diameter. See column 4, lines 58-67 and column 8, lines 32-35. Jang discloses determining the longitudinal position of a branching segment in column 4, lines 58-67, and as admitted by applicant on page 11, lines 3-7 of the preliminary amendment filed April 2, 2004. Jang also discloses that the ultrasound transducer (75) is fixed to the distal end of a drive shaft (45), and the proximal end of the drive shaft (45) is connected to a drive motor for rotating the drive shaft. See column 9, lines 4-6 and column 10, lines 17-19. Because the ultrasound transducer will rotate with the drive shaft to provide 360 degree imaging, the radial position of the branching segment will also be determined. See column 5, lines 44-60 and column 10, lines 26-39 for the ultrasound transducer (75) being used to image changes in stent diameter, which also clearly indicates the transducer's ability for radial position determination. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Jang et al. to modify the stent delivery system of Von Oepen to include an ultrasound imaging transducer disposed inside the

expansion device in order to determine exactly where the diseased segment of the blood vessel begins and ends and to correctly position the stent such that the side hole is positioned at the ostium of a branch vessel. This would replace the completely separate x-ray contrast means and x-ray screen for visual monitoring used by Von Oepen for positioning the side hole, thus simplifying the procedure. In addition, by making the ultrasound transducer adapted to axially translate along and rotate relative to the longitudinal axis, as taught by Jang et al., the examiner contends that use of this ultrasound transducer instead of x-ray will provide the surgeon with more accurate, informative and controllable images of the diseased vessels for side hole positioning.

Claims 9 and 10, see Figure 2 for a guidewire (31) at least partially disposed in the lumen. With respect to claim 10, it is unclear what "said passageway" is referring to.

Claim 11, see column 9, lines 4-6 and column 10, lines 17-19 for a controller in the form of a drive motor being coupled to the transducer (75) via drive shaft (45).

Claim 22, see rejection to claim 1, supra. Because the ultrasound imaging transducer (75) allows for the determination of both longitudinal and radial positions of an ostium of a branch vessel, the stent (20) can be delivered within the body lumen such that the side hole (22) can be aligned with the ostium, and thereby meet the functional limitations of the claim.

Claims 23,24,26 and 27 are broader in scope than the corresponding claims 1, 3, 9-11,22 that have been rejected supra.

Claims12,25,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen in view of Jang et al. and Solomon (USPN 5,846,204 as cited in applicant's IDS).

Von Oepen, as modified by Jang et al., discloses a stent delivery system with all the elements of claim 12, but is silent to a transducer housing coupled to the transducer, the housing having distal and proximal ends and a passage through the housing between the ends, and a positioning guidewire at least partially disposed in the catheter lumen and passing through the transducer housing passage. See rejection to claim 1, supra. Solomon teaches, in Figure 1, a rotatable ultrasound imaging catheter (100) with a transducer housing (combination of 104 and 108) coupled to a transducer (106) and drive cable (102). Between proximal and distal ends of and through the housing (104 and 108) is a passage (114). A guidewire is accepted through the passage (114) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire for three-dimensional imaging. See column 5, lines 1-14. Because the guidewire sleeve portion (108) is *integral with* the housing portion (104), the transducer housing is rightfully interpreted as including both portions (104 and 108) (column 5, lines 19-22). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solomon to modify the stent delivery system of Von Oepen and Jang et al. to include a transducer housing with a passage coupled to the transducer (75) and drive cable (45) in order to prevent unintended deflection of the transducer as it is rotated around the guidewire disposed in the passage. This ensures that the ultrasound transducer travels in a predetermined path

around the guidewire maintained in the passage, which is configured to maintain the planar surface of the transducer substantially parallel with a portion of the guidewire that is located within the passage. See column 6, lines 22-33. By including the housing of Solomon to the transducer and drive cable of Jang et al., the need to remove the guidewire from guidewire/ultrasound lumen (103) before inserting the imaging device with transducer is eliminated. The imaging device with transducer can be positioned directly over the guidewire through the passage and advantageously reduce operating time.

Response to Arguments

Applicant's arguments filed April 2, 2004 have been fully considered but they are not persuasive.

Applicant's arguments directed to Claims 1,3,9-11, 22,23,24,26,27 with respect to Von Oepen and Jang have been considered but the rejections to the claims stand.

Applicant argues that Von Oepen and Jang, alone or in combination, fails to disclose or teach an ultrasound "positioned for transmitting and receiving ultrasound signals through said side hole" of the stent as required by claim 1. Examiner disagrees with applicant's interpretation of the combination of Von Oepen and Jang with respect to the "metes and bounds" of the claim.

Claim 1 requires the following physical elements including:

A stent delivery system comprising:

a catheter comprising a catheter body having a distal end, a proximal end, a longitudinal axis and a lumen;

an expansion device disposed near the catheter body distal end;

a stent having a wall comprising struts and connectors forming multiple passageways and further comprising a side hole adapted to provide access to a side branch, the stent being disposed over the expansion device;

and an ultrasound transducer disposed near the catheter body distal end and positioned for transmitting and receiving ultrasound signals so that positions may be determined.

The language of "through said side hole such that both a longitudinal and an axial radial position of the ostium of the branch vessel is determined in relation to said side hole" is directed to a method step for determining the relationship between a feature of the stent and the in vivo vasculature. Examiner contends that the combination of Von Oepen and Jang provides all the elements of the stent delivery system as claimed. While examiner agrees with applicant, that the combination of Von Oepen and Jang fails to positively disclose the method step for determining the position of the side hole with respect to a branched vessel of the ostium, the system of Von Oepen as modified by Jang is fully capable of providing the function as claimed by applicant.

Jang et al. teaches a stent delivery system, which includes an ultrasound transducer (75) disposed inside an expansion device (as required by claim 3) in order to determine exactly where the diseased segment of the blood vessel begins and ends and to image

the stent for correct positioning and diameter. See column 4, lines 58-67 and column 8, lines 32-35. Jang discloses determining the longitudinal position of a branching segment in column 4, lines 58-67.

Applicant further argues that Jang fails to provide the method steps of aligning a feature of the prosthesis with the opening into the branch vessel, thus covering the branch vessel opening with the prosthesis. Again, applicant's arguments are directed to method steps for using the system as claimed. As set forth supra, the examiner has provided a system that is capable of providing for the steps as argued by applicant. First, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Jang et al. to modify the stent delivery system of Von Oepen to include an ultrasound imaging transducer disposed inside the expansion device in order to determine exactly where the diseased segment of the blood vessel begins and ends and is capable for correctly positioning the stent such that the side hole is positioned at the ostium of a branch vessel. This would replace the completely separate x-ray contrast means and x-ray screen for visual monitoring used by Von Oepen for positioning the side hole, thus simplifying the procedure. In addition, by making the ultrasound transducer adapted to axially translate along and rotate relative to the longitudinal axis, as taught by Jang et al., the examiner contends that use of this ultrasound transducer instead of x-ray will provide the surgeon with more accurate, informative and controllable images of the diseased vessels for side hole positioning.

With respect to claims 12,25,28, applicant argues that Solomon fails to disclose or suggest a passage that is aligned with the central axis housing 104. Examiner respectfully disagrees with applicant's position. The language of "an ultrasound transducer housing having a distal end, a proximal end, and a passage extending along a central axis of said housing between said distal and proximal ends, said housing having a transducer coupled thereto" fails to distinguish over the same as illustrated by Solomon. Applicant argues "aligned" limitation that is not present in the claim. Moreover, the guidewire passage is oriented with respect to the central axis of the housing as broadly claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
7/7/2006